IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	**MDL No. 2804** **Case No. 17-md-2804** **Judge Dan Aaron Polster**

This document relates to:
The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004

The County of Summit, Ohio, et al. v. Purdue Pharma L.P. et al., Case No. 18-OP-45090

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE MEREDITH ROSENTHAL'S OPINIONS AND PROPOSED TESTIMONY

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Defendants move under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and its progeny to exclude Professor Meredith Rosenthal from offering opinions and testimony regarding causation and damages. Because Rosenthal's opinions suffer serious methodological flaws that render them unreliable and irrelevant to a fact finder's evaluation of the issues, they should be excluded.

First, Rosenthal's opinions do not tie to Plaintiffs' theory of the case. Rosenthal purports to calculate the percentage of opioid prescriptions nationwide resulting from all physician detailing[1] by all opioid manufacturers (not just Defendants). In so doing, she includes ***all*** detailing visits in her analysis, regardless of whether they were lawful or unlawful, or if the resulting prescription was medically necessary; this is inconsistent with Plaintiffs' claims, which are centered—as they must be—on harm resulting from Defendants' ***un***lawful conduct. Moreover, she assumes without any basis that these detailing contacts were uniform in substance and scope. In addition, although Plaintiffs' allegations rely heavily on purported collaboration with third-party groups and key opinion leaders, she fails to account for this conduct in her analysis. And her opinions are impermissibly premised on aggregate proof, where she calculates the effect of ***all manufacturers'*** detailing on ***total opioid sales***, making no attempt to determine whether any specific Defendant's promotion increased opioid sales in the Track One Counties. Her opinions are thus conceptually flawed, irrelevant, and unhelpful to the trier of fact.

Second, there is no factual support for Rosenthal's assumption that ***all*** detailing was unlawful. In fact, Plaintiffs' experts (and Rosenthal herself) refute such a notion. Courts routinely exclude expert opinions that lack record support—and Rosenthal's opinions are no exception.

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[1] "Detailing" means a sales representative's physical visit to a prescriber to convey information about the product in question. (Ex. 1, Rosenthal Report at ¶ 56; Ex. 2, Rosenthal Dep. at 44:11–19.)

Third, Rosenthal makes absurd assumptions designed to give the appearance of a causal relationship between detailing and opioid sales. For example, she uses a "negative depreciation rate," which assumes that a detailing visit to a doctor in the 1990s had an ever-increasing impact on opioid prescribing that continues to grow to this day. This assumption has ***zero*** support in economic literature and constitutes nothing more than a feeble attempt to "overfit" her model to ensure her conclusions. Case in point: her model is so flexible that one could replace opioid sales with another variable—like average annual attendance at Cleveland Indians games—and her model would find a causal relationship between detailing and baseball game attendance.

And ***fourth***, Rosenthal's methodology suffers numerous incurable methodological failures that render all of her opinions unreliable. Indeed, she relies on and makes medical judgments that she has no qualifications to support and her models fail to account for numerous economic issues inherent in regression analysis. Other methodological flaws permeate her opinions.

I. BACKGROUND

Throughout discovery, Defendants pressed Plaintiffs for actual, specific evidence showing that each Defendant caused inappropriate opioid prescriptions that in turn harmed the Track One Counties. Time and again, however, Plaintiffs resisted this discovery because they were relying on "statistical and aggregate evidence." (Doc #606, Discovery Ruling No. 1.) Based on Plaintiffs' representations about how they sought to prove their case, Special Master Cohen allowed Plaintiffs to avoid or narrow individualized discovery, but admonished that they did so at their own peril:

> The ultimate question of the requisite level of proof is an issue the Court may have to answer at a future stage of litigation, perhaps through orders resolving summary judgment or *Daubert* motions. At this juncture, it is possible only to observe that Plaintiffs' current discovery productions must equal or surpass the proofs that will eventually be required. … [I]f Plaintiffs are incorrect, and the Court ultimately requires more granular proof of causation than Plaintiffs produce in discovery, then Defendants will rightly point to Plaintiffs' responses to the RFPs as a basis for defense judgment. (*Id*. at 5.)

We have now reached the juncture where Plaintiffs' approach is put to the test—and it fails. Defendants' separate summary judgment motions address the legal deficiency of Plaintiffs' aggregate models given their burden to show that a Defendant's conduct proximately caused the harms alleged by the Track One Counties. This *Daubert* motion separately addresses how—even assuming that aggregate proof might be sufficient for certain of Plaintiffs' claims (and it is not)—Rosenthal's models fail to meet the standards for admissibility of expert testimony.

Plaintiffs asked Rosenthal to determine whether the manufacturers' unlawful promotion of opioids since 1995 caused an increase in opioid use, and if so, to what degree. (Ex. 1, Rosenthal Report at ¶ 8.) Plaintiffs' counsel instructed her to assume that ***every instance of physician detailing was unlawful***. Rosenthal prepared regression analyses supposedly designed to measure the effect of that detailing on the number of milligrams of morphine equivalent ("MME") sales for all opioids at issue. (Ex. 1, Rosenthal Report at ¶¶ 58–60.) As discussed below, however, Rosenthal's analyses cannot be squared with Plaintiffs' theory of the case and instead heavily rely on incorrect and unproven assumptions. These fatal flaws render her opinion irrelevant and unreliable, and thus, inadmissible.

II. ARGUMENT

A. Rosenthal's Opinions Are Not Relevant as They Do Not "Fit" Plaintiffs' Theory of the Case.

To be admissible, expert testimony must "help the trier of fact to understand the evidence or to determine a fact in issue." F.R.E. 702(a). In scrutinizing proposed expert testimony, courts routinely exclude causation experts who offer opinions that fail to connect the alleged misconduct to the alleged injury. For example, in *Botnick v. Zimmer, Inc.*, this Court held that *Daubert* required the plaintiff's causation expert's testimony to "exhibit relevancy, ***connecting his theory*** of an alleged defect in the medical device to [the plaintiff's] injury." 484 F. Supp. 2d 715, 721

(N.D. Ohio 2007) (emphasis added). In excluding the expert, the Court determined that the testimony lacked that critical connection, as it was "not driven, as it must be, by the context of the issues in this case." *Id*. Other federal courts have reached similar conclusions. *See Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp*., 582 F.3d 1227, 1234–35 (11th Cir. 2009) (expert excluded because opinion was inconsistent with plaintiffs' liability theory); *Grp. Health Plan, Inc. v. Philip Morris USA, Inc*., 344 F.3d 753, 761 (8th Cir. 2003) (same).

Here, Rosenthal's opinions are inconsistent with Plaintiffs' theory and thus will not help the trier of fact. Plaintiffs' theory is that the manufacturers engaged in "a massive marketing campaign ***premised on false and incomplete information***," in which they "relentlessly and methodically, ***but untruthfully***, asserted that the risk of addiction was low when opioids were used to treat chronic pain." (Doc #1466, Summit 3AC at ¶ 10 (emphases added).) In addition, Plaintiffs assert that each manufacturer Defendant carried out this illegal marketing scheme by disseminating its allegedly ***false*** marketing messages through purportedly neutral mediums including so-called "front groups," "key opinion leaders" ("KOLs"), and continuing medical education ("CME") programs. (*Id*. at ¶ 346.) Consequently, Plaintiffs seek to recoup the "extraordinary costs and losses that are related directly to Defendants' ***illegal*** actions." (*Id*. at ¶ 21 (emphasis added).)

Even if Rosenthal's model was reliable—and as illustrated below, it is not—her causation and damages opinions do not fit Plaintiffs' theory. Her opinions should be excluded for the following four reasons, each of which serves as an independent basis for exclusion:

- Rosenthal's model compares the effect of both lawful and allegedly unlawful detailing to opioid prescriptions. She does not attempt to isolate what percentage of opioid prescriptions are linked to any unlawful versus lawful conduct or what percentage of prescriptions are for medically necessary treatments and thus would have been prescribed anyway.

- Rosenthal assumes without any basis that all detailing conduct was the same.

- Rosenthal does not attempt to measure Defendants' purported marketing through front groups, KOLs, or CME programs.

- Rosenthal's direct model relies on aggregate proof, which does not permit assigning liability to any Defendant because it does not show how any particular Defendant's alleged misrepresentations resulted in any opioid prescriptions.

1. *Rosenthal Does Not Purport to Measure the Effects of Defendants' Allegedly Unlawful Conduct.*

Based on an instruction from counsel, Rosenthal assumes that ***all*** detailing by the manufacturer Defendants from 1995 to the present was unlawful. (Ex. 1, Rosenthal Report at ¶ 75; Ex. 2, Rosenthal Dep. at 46:5–9, 149:24–150:7.) Notwithstanding that there is physician detailing and other forms of promotion that are perfectly lawful, Rosenthal does not exclude lawful detailing contacts from her model—or even attempt to do so. Nor has she attempted to measure the number of medically unnecessary prescriptions written due to lawful versus unlawful conduct; she simply assumes that Plaintiffs can recover for all opioid sales "whether or not they resulted in medically necessary prescriptions." (Ex. 2, Rosenthal Dep. at 150:8–152:21.) Indeed, she conceded the following point: "Q. Stated differently, your model will calculate causation by defendants' marketing even for medically necessary prescriptions? A. ***It does not distinguish.*** And to be clear, ***whether or not there were medically necessary prescriptions caused by the misconduct, I can't say for sure***." (*Id.* at 152:22–153:5 (emphasis added).)

Rosenthal's assumption that all detailing was unlawful—which, as discussed below, has no factual support—and her assumption that all prescriptions resulted from unlawful conduct as opposed to proper medical judgment serve as the foundation for her causation analysis, and thus, all of her opinions concerning the effects of opioid promotion hinge on them. Plaintiffs' claims here, however, relate exclusively to Defendants' alleged ***un***lawful promotion and those prescriptions caused by such unlawful promotion. Rosenthal's model does nothing to test or support these claims. Instead, she assumes an overly broad set of facts that are inconsistent with

Plaintiffs' theory and represent a dramatic diversion from reality. Thus, Rosenthal's opinions on causation will not assist the trier of fact in assessing whether and to what extent Defendants' alleged unlawful promotion affected opioid prescriptions or sales.

Boca Raton Community Hospital, Inc. shows as much. There, a group of hospitals sued a hospital chain, alleging that the defendant rigged a Medicare program designed to repay hospitals for out-of-pocket-costs by inflating its charges to the program. 582 F.3d at 1229. The plaintiffs' expert attempted to show that the defendant's improper overcharging caused the threshold to increase by offering an opinion as to what the threshold would have been absent the defendant's charges. *Id*. at 1231. The district court, however, excluded the testimony because the expert made no attempt to determine what the defendant could have lawfully charged. *Id*. at 1231–32. And the Eleventh Circuit affirmed "because [the expert's] injury and damages opinion was not confined to charges that its liability theory would consider unlawful, it was too broad." *Id*. at 1233–34.

Likewise here, Rosenthal's direct model fails to distinguish lawful from unlawful conduct, even though Plaintiffs are not seeking and cannot obtain recovery for lawful acts. Accordingly, her opinion does not fit the theory of the case and should be excluded.

2. *Rosenthal Impermissibly Treats All Detailing Contacts as Uniform.*

To measure the manufacturers' promotion, Rosenthal counts ***only*** the total number of times each manufacturer Defendant's sales representatives detailed prescribers, regardless of what information was actually communicated in those detailing visits. (*See, e.g.*, Ex. 2, Rosenthal Dep. at 42:23–43:22.) By relying strictly on an arithmetic count of visits in lieu of evaluating the substance and context of those visits, Rosenthal effectively assumes that all detailing conduct is the same. Indeed, she admits that her model includes detailing contacts in which (1) the sales representative had no interaction with a prescriber; (2) the detail did not result in any change in the prescriber's behavior; (3) the prescriber's prescription rate actually decreased after the detail;

(4) the prescriber never prescribed the medicine covered in the detail; (5) the prescriber was a lead author of journal articles discussing the risks of opioid addiction; (6) the prescriber was an oncologist or hospice provider prescribing opioids for end-of-life cancer pain (which even Plaintiffs agree is appropriate); or (7) the prescriber was a surgeon or performs trauma intervention in an emergency room. (Ex. 2, Rosenthal Dep. at 735:23–740:4.) Stated otherwise, Rosenthal's model includes all detailing contacts regardless of who was detailed, what was said, whether there was an effect on prescribing behavior, and if a meeting actually occurred. (*Id*. at 740:14–741:3.)

Further, Rosenthal's model also includes detailing that was solely "rivalrous," meaning detailing that was designed to convert doctors who were prescribing one kind of opioid to another. (*Id*. at 90:3–16.) By definition, such marketing has no effect on overall number of opioid prescriptions. And as the discovery record shows, for some medications and some manufacturers, particularly ones that entered the market later in time, marketing efforts were ***entirely*** rivalrous.

Rosenthal's failure to differentiate the nature and effect of each manufacturer's unique detailing efforts results in opinions that fail to reflect reality and thus are unreliable. *See Pomella v. Regency Coach Lines, Ltd.*, 899 F. Supp. 335, 342 (E.D. Mich. 1995) (excluding testimony when expert assumed uniform road conditions when the evidence showed that was not the case).

3. *Rosenthal's Model Does Not Measure the Effects of Defendants' Alleged Unlawful Promotion through Front Groups, KOLs, and CME Programs.*

Rosenthal's sole focus on in-person detailing fails to account for the alleged unlawful promotion through front groups, KOLs, and CMEs. Plaintiffs contend that the manufacturers used these mediums to disseminate false information through "seemingly neutral and credible third parties." (Summit 3AC at ¶¶ 171, 347.) Yet Rosenthal fails to account for these activities at all. (*See* Ex. 2, Rosenthal Dep. at 145:6–18, 161:10–163:15.) According to Rosenthal's direct model, detailing alone explains 99 percent of all MME sales over the preceding two decades, meaning

that the other conduct and activities that Plaintiffs challenge and spent considerable time and resources investigating had no discernible effect. (*Id*. at 388:19–389:4, 526:17–21.)

Rosenthal's decision to examine only detailing and to ignore other forms of promotion results in overly broad causation opinions that conflict with Plaintiffs' theory. Further, this is not something that Rosenthal can correct easily. As Rosenthal herself admitted, she was not "asked to look at" how KOLs influenced prescribing standards—which is "more of a sort of qualitative piece" (*id.* at 145:6–18)—and if the conclusion reached for the manufacturers is that detailing is entirely lawful but they engaged in other conduct found to be unlawful (like influencing KOLs), "[i]t would require a new but-for analysis." (*Id.* 164:20–165:18.)

At the end of the day, even if Rosenthal's model was reliable, it does nothing more than measure the effect of both lawful and allegedly unlawful detailing on opioid prescriptions in the aggregate. Put differently, Rosenthal's opinions are reduced to the unobjectionable but misguided conclusion that detailing correlates with sales. Rosenthal's opinions do not tie to Plaintiffs' theory of liability, and thus, her opinion and proposed testimony should be excluded.

4. *Rosenthal's Market-Share Model Is Impermissibly Premised on Aggregate Proof.*

Rosenthal's opinions also should be excluded because her model does not connect any particular Defendant's alleged misconduct to any opioid prescription that Plaintiffs claim such misconduct caused. Indeed, Rosenthal's model "is not designed to assign liability to individual manufacturers" (Ex. 2, Rosenthal Dep. at 164:4–9)—the very causation issue her testimony presumably should address. Indeed, Rosenthal concedes that she is "interested in understanding how marketing ***as a whole*** drove sales in this market." (*Id.* at 80:16–18.) *See Petre v. Norfolk S. Ry. Co.*, 458 F. Supp. 2d 518, 543 (N.D. Ohio 2006) (holding that a plaintiff cannot prove proximate cause where "the cause of injury may be reasonably attributed to things for which the

defendant is not responsible as to things for which he is responsible.") (citations omitted). Instead, Rosenthal's models consider only the aggregate effect of marketing (Ex. 2, Rosenthal Dep. at 215:4–18)—that is, "total marketing [versus] total sales" for all manufacturers at the national level. (*Id.* at 122:11–23.)

In fact, Rosenthal admits that she does not even "know whether an individual manufacturer-level model would be feasible" (*id.* 160:7–11) and that she "ha[s] not conducted [her] analysis at the level of an individual defendant" (*id.* 500:11–19.) She also clarified that "the purpose of Table 3" in her report—which ostensibly breaks down the aggregate harm by each manufacturer Defendant—"is not to allocate [liability] to defendants" but to provide "an aggregate measure of impact associated with defendants' promotion." (*Id.* 441:13–442:1, 439:20–440:1; *see* Ex. 1, Rosenthal Report at ¶ 52 & Table 3.) Thus, even her Defendant-by-Defendant breakdown is meant to show only that she "could remove the conduct of one of the defendants and still calculate aggregate impact." (Ex. 2, Rosenthal Dep. at 441:23–442:1.)

Consequently, Rosenthal's models do not allow her to assign liability to individual manufacturers. Indeed, she testified as follows:

> Q. For a manufacturer that was not part of the market before it grew, and came into the market after it had been expanded, why is it the case in your model that that manufacturer is part of the aggregate analysis and not subject to some other type of causation allocation?
>
> A. ***Nowhere in my assignment was I asked to look at liability for individual manufacturers. I'm only trying to quantify aggregate impact. To the extent that I subtract individual defendants, it's really only to get to a different whole, it's not to assign liability to an individual defendant.***

(Ex. 2, Rosenthal Dep. 340:23-341:13 (emphasis added).) Thus, her opinions do not (and cannot) assist the fact-finder in identifying which (if any) prescriptions were caused or written by any particular Defendant's allegedly false marketing. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 94 (2d Cir. 2015) ("a RICO plaintiff must

always show that the defendant's conduct caused an *actual*, quantifiable injury"). As she admits, her model would break down if it were disaggregated by drug, by manufacturer, by detailing content, by detailing duration, or by any other basis less than the opioid-class level. (*See*, *e.g.*, Ex. 2, Rosenthal Dep. at 196:10–25, 202:3–12, 204:15–205:25, 201:12–211:2, 332:1–24, 344:3–6.)

In sum, Rosenthal's opinions are not admissible because they do not fit Plaintiffs' claims.

B. Rosenthal's Core Assumption that All Manufacturer Promotion Was Unlawful and All Resulting Prescriptions are Tainted has No Basis in Fact.

Rosenthal's core assumption that all Defendant manufacturer promotion was unlawful is provably wrong. Even Plaintiffs' own experts refute such a notion. Professor David Cutler authored an article explaining that drug promotion can increase patient welfare. *See* Ex. 3, David M. Cutler et al., *The Value Of Antihypertensive Drugs: A Perspective On Medical Innovation,* Health Affairs 26, no. 1 (2007). Matthew Perri III, Plaintiffs' marketing expert, acknowledges that pharmaceutical promotion serves the important purpose of providing information to prescribers to keep "their drug knowledge and their disease knowledge" current. (Ex. 4, Perri Dep. at 111:14–23.) And David Kessler, Plaintiffs' regulatory expert, opines that certain detailing activities are appropriate. (Ex. 5, Kessler Dep. at 759:17–760:8.) Even Rosenthal concedes that "there is such a thing as lawful marketing, and it does generate sales. Some of those sales may be medically necessary, some may be medically unnecessary, even if there's no unlawful conduct." (Ex. 2, Rosenthal Dep. at 153:25–154:6.)

Notwithstanding these opinions, Rosenthal's own beliefs, and the fact that the FDA expressly permits pharmaceutical promotion, Rosenthal's model improperly treats all detailing as unlawful and all resulting MME sales as caused by unlawful conduct. For example, Rosenthal assumes that it is unlawful for a Defendant manufacturer's sales representative to do nothing more than relay information from an FDA-approved package insert or corrective statements. (Ex. 2,

Rosenthal Dep. at 215:19–218:14.) Rosenthal blindly followed counsel's instruction to assume that all promotion was unlawful—an assumption that lacks factual support—and thus, her opinions are unreliable. *See In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 146 (E.D. Penn. 2015) ("Dr. Rosenthal states that she was 'instructed by counsel to work from the theory' that Class membership is a function of who pays for the drug at the time of the transaction. … An instruction from counsel is not a sound basis on which to draw an economic conclusion."); *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) ("It is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record.").

C. Rosenthal Makes Baseless Assumptions Designed to Ensure Her Conclusions.

Rosenthal's direct regression model purports to show that over 99 percent of opioid prescriptions were dispensed solely on the basis of manufacturer detailing. (Ex. 1, Rosenthal Report at ¶ 72; Ex. 2, Rosenthal Dep. at 388:22–389:4.) This conclusion not only is at odds with Plaintiffs' claims concerning front groups and KOLs but also shows that Rosenthal contorted and "overfit" her model to ensure that the aggregate detailing data mapped perfectly onto the aggregate level of MME sales, ignoring economic literature and common sense.

For example, Rosenthal estimated a ***negative*** depreciation rate for promotion, which means that a detail to a doctor will cause that doctor's opioid prescribing to increase exponentially over time. (Ex. 2, Rosenthal Dep. at 247:24–249:10.) Stated differently, Rosenthal's model ***increases*** the effect of marketing over time: thus, a detail in 1995 has more impact on prescribing today than it did in 1995, 2000, or 2010—and will have even more impact tomorrow. (*See id.* at 253:17–254:17.) Not only is such a theory of the forever-ascending potency of marketing illogical, but Rosenthal expressly recognized that no economic literature supports it. (*Id.* at 259:25–260:6.)

Cutler admitted during his deposition that he has never observed a negative depreciation rate in the literature. (Ex. 6, Cutler Dep. at 178:19–179:2.) Henry Grabowski also testified that

he has never seen a negative depreciation rate, as consultants confirmed through a diligent literature search. (Ex. 7, Grabowski Dep. at 38:12–39:7.) And authoritative literature establishes that people actually forget marketing messages if they are not repeated over time (*i.e.,* the effects of marketing depreciate over time). *See* Ex. 8, Mark Hirschey, *Intangible Capital Aspects of Advertising and R&D Expenditures*, The Journal of Industrial Economics 30(4) at 375 (1982) ("Consumers tend to forget brands and continuous advertising is needed to maintain a given rate of sales.")[2]

Courts routinely exclude purported expert opinion lacking support in literature. In *Ashland Hospital Corp. v. Affiliate FM Insurance Co*., the court excluded testimony, finding that the expert was not aware of any data, studies, research, tests, or journals to support his opinion. The court further explained that "[t]his lack of methodology and lack of supporting literature are grounds to exclude an expert opinion." 2013 WL 3213051, at *6 (E.D. Ky. June 24, 2013).[3]

Exclusion is particularly appropriate here. Indeed, because Rosenthal manipulated her direct model to ensure her conclusions, it contains so much flexibility that, if one were to replace MME sales in her model with data from NASA concerning the monthly average of daily sunspots, the price of gold, or the average yearly attendance at Cleveland Indian baseball games, one applying her model would find a causal relationship between physician detailing on the one hand and sunspots, gold prices, or baseball attendance on the other. (Ex. 9, Kyle Dep. at 151:3–21; Ex.

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[2] Another example of Rosenthal overfitting her model is her decision to alter her direct model at three arbitrary time periods to account for different degrees of promotional effectiveness. (Ex. 1, Rosenthal Report at ¶¶ 71–72; Ex. 2, Rosenthal Dep. 289:21–290:5.) This shows a lack of reliability.

[3] *See also Nelson v. Tenn. Gas Pipeline Co.,* 243 F.3d 244, 251 (6th Cir. 2001) (the lack of peer review and publication of the expert's methodology was "plainly relevant" to the reliability of his theory); *Mohney v. USA Hockey, Inc.*, 300 F. Supp. 2d 556, 572 n. 11 (N.D. Ohio 2004) (the novelty of the expert's analysis made the lack of testing "glaring and egregious," and "neither the Court nor any expert testifying in this case has been able to identify any tests or scholarly literature" that mention the analysis the expert opined on).

10, Kyle Report at ¶ 135; Ex. 11, Ketchum Report at ¶ 179.) Conversely, because she fits her model to the data, her model does not accurately predict real-world events that may have influenced opioid prescribing, like changing medical standards and drug reclassification. (*See* Ex. 2, Rosenthal Dep. at 311:18–314:3 (model predicts 1997 American Pain Society statement supporting opioid use for pain actually *decreases* MME sales in a way that "did not conform to her expectations"); *id*. at 316:18–317:19 (rescheduling hydrocodone from Class III to Class II "counterintuitively" suggested an increase in MME sales).) Such a model that prioritizes fit over logic deserves no credence and cannot be offered to a jury as a reliable means to prove causation.

D. Rosenthal's Methodology Suffers from Other Serious Methodological Flaws.

1. *Rosenthal's "Thought Experiment" Relies on Unfounded Medical Opinions and Arithmetic.*

Equally egregiously, in her report, Rosenthal conducts what she describes as a "thought experiment" to test whether the increase in opioid MMEs in the United States could be explained by "previously 'under-treated'" pain—*i.e.*, medically appropriate opioid prescriptions. (*See* Ex. 1, Rosenthal Report at ¶¶ 90–102.) To do this, Rosenthal first takes Plaintiffs' clinical experts' definition of a medically appropriate opioid prescription to conclude that opioids are appropriate for terminal cancer, trauma, and surgery patients only. (*See id.* at ¶ 92.) For each of these three categories, she then multiplies (1) the number of patients treated, (2) the daily dose in MMEs, and (3) the duration of treatment in days (the latter two of which she estimates based on her review of medical literature). (*See id.* at ¶ 94.) She then sums the MMEs for the three categories and compares it to the total MMEs sold. (*See id.* at Table 6.)

Rosenthal's "thought experiment" is improper because it depends on other experts' flawed and unsupported medical assumptions of which opioid uses are medically appropriate. Rosenthal readily admits that she is not a medical doctor or an expert in pain management, addiction

medicine, or opioid use disorder. (Ex. 2, Rosenthal Dep. at 14:2–16:3.) Thus, she concedes that "[a]ll of the underlying assumptions in this section have been developed in reference to the opinions of the plaintiffs' clinical experts, including Dr. Schumacher and Dr. Parran." (Ex. 1, Rosenthal Report at ¶ 92.) Rosenthal's reliance on Dr. Parran is improper given that Plaintiffs have withdrawn him as a witness. *See Mike's Train House, Inc. v. Lionel, L.L.C.*, 472 F.3d 398, 409 (6th Cir. 2006). And Rosenthal's reliance on Dr. Schumacher is improper as this Court and others have repeatedly confirmed that "[a] scientist, however well credentialed [s]he may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *In re Whirlpool Corp. Front-Loading Washer Prod. Liab. Litig.*, 45 F. Supp. 3d 724, 741 (N.D. Ohio 2014) (quoting *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002)).

Rosenthal's reliance on Plaintiffs' clinical experts is particularly problematic because they endorse an extremely narrow view of the permissible uses of opioids—a view that defies the FDA-approved uses for such products, all prevailing medical standards during the relevant time period, and even current medical standards that evolved in light of the opioid crisis, like those put forth by the CDC. (Ex. 10, Kyle Report at ¶¶ 149–153.) Consequently, Rosenthal's "appropriate use" analysis includes no room at all for the use of opioids to treat chronic pain, or even for cancer patients outside of hospice or non-cancer patients in hospice. (Ex. 2, Rosenthal Dep. at 636:7–19.) In fact, Rosenthal contradicts her own analysis, conceding that, "according to their label," "opioids have legitimate medical uses for certain diseases and conditions" and agreeing "that the approved labels include those conditions for which the FDA has deemed them appropriate." (*Id.* at 21:16–22:1.) In sum, Rosenthal adopts the flawed opinions of Plaintiffs' other experts who "exercised 'independent judgment'"—dubious as it may be—"that [is] 'beyond [her] ken.'" *See Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 666 (S.D.N.Y. 2007) (citation omitted).

Beyond blindly adopting Plaintiffs' clinical experts' judgments, Rosenthal also makes her own medical assessments—decisions she has no qualifications to make—to cherry-pick exemplar dosages for the three narrow treatments she picks from medical guidelines. For example, to calculate the appropriate opioid dosage for patients suffering from surgical and trauma pain, Rosenthal selects 30 MMEs over seven days based on MD Anderson Cancer Center's Postoperative Pain Management Guidelines. (Ex. 1, Rosenthal Report at ¶ 99; Ex. 2, Rosenthal Dep. at 710:5–18.) Rosenthal not only fails to explain why she chose these Guidelines, but a review of the Guidelines during her deposition revealed that Rosenthal selected dosages within a provided range (*i.e.*, 20 to 40 mg of immediate-release hydrocodone) after consulting with counsel and other experts. (Ex. 2, Rosenthal Dep. at 716:12–24.) As Rosenthal admitted, she "was advised to focus on hydrocodone and was told that 30 milligrams was a reasonable baseline. Again, assuming that there's some patients who will only get 20, some patients who will get more." (*Id.*)

Once stripped of the medical judgments that she is not qualified to make, Rosenthal's "thought experiment" does nothing more than apply arithmetic, multiplying Rosenthal's selected "appropriate" doses for cancer, trauma, and surgical patients by data reflecting the number of such patients in the Track One Counties. But an "expert is precluded from offering testimony that is not based on any specialized knowledge, but rather involves 'basic calculations.'" *Scott v. Chipotle Mexican Grill, Inc.*, 315 F.R.D. 33, 56 (S.D.N.Y. 2016) (citations omitted). Indeed, at her deposition, Rosenthal could not identify a single treatise or methodological paper supporting the work she did in applying her "thought experiment." (Ex. 2, Rosenthal Dep. at 627:9–628:2.) Rather than employing a peer-reviewed methodology, Rosenthal created her own, which "had not been tested, had not been subjected to peer review, had no controlling standards, had no demonstrable showing of support within the scientific community, and was produced solely for

purposes of the instant litigation." *Kentucky Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 916 (6th Cir. 2009). She then applied it to the unsupported medical judgments of other experts and her own untrained medical assessments. Such an opinion is inadmissible under *Daubert* and must be excluded.

2. *Rosenthal's Regression Models Ignore Other Basic Economic Principles.*

Rosenthal's direct and indirect regression models also are fundamentally flawed because they ignore basic economic principles and statistical theories to arrive at outcome-driven results.

To measure the effect of detailing on prescribing, Rosenthal employs what is called a "time-series" regression, which examines patterns over time for a single unit of analysis—here, MME sales. (Ex. 1, Rosenthal Report at ¶ 58.) Like all regression models, time-series models require certain assumptions about the underlying data, one of which is that the data be "stationary," meaning that fluctuations in the data moving in the same direction *through* time are not a function *of* time. *See* Ex. 12, R. Carter Hill and William E. Griffiths, *Principles of Econometrics* at 476 (John Wiley & Sons, Inc., 4th ed. 2011). Rosenthal admits that "nonstationarity" is one of the "well-known limitations of any time series model" (Ex. 2, Rosenthal Dep. at 134:10–25), and can produce "spurious results" (*id*. at 138:16–20)—meaning that an "apparently significant regression results from unrelated data." *See* Ex. 12, *Principles of Econometrics* at 482. And Rosenthal concedes that nonstationarity could cause her model to overstate the effect of promotion on prescriptions. (Ex. 2, Rosenthal Dep. 139:19–24.)

At her deposition, Rosenthal admitted that she did not know if MME sales—the dependent variable in her model—were stationary or nonstationary. (*Id*. at 139:13–15.) And since she did not know if her data inputs were stationary, she made no effort to test for or correct any nonstationarity. (*Id*. at 139:25–140:4.) Because Rosenthal did not even test to see if her model overcomes the stationarity problem inherent in all time-series models, she cannot know if she

overstates the effect of promotion on sales. Thus, her opinion is unreliable. *See Dover v. British Airways, PLC (UK)*, 254 F. Supp. 3d 455, 463–65 (E.D.N.Y. 2017) (concluding that expert's explanation on nonstationarity of the underlying data was insufficient).

Rosenthal's model also suffers from endogeneity bias, which likewise could cause her to overstate the effect of promotion on prescribing. Endogeneity occurs when there is a correlation between the explanatory variable and error term. *See* Ex. 13, Peter Kennedy, *A Guide to Econometrics* at 139 (6th ed. 2008). As relevant here, detailing (the explanatory variable) and opioid sales (the dependent variable) are simultaneously determined, or endogenous, because pharmaceutical companies generally send sales representatives to doctors who are prescribing their products rather than to new doctor prospects. Consequently, one does not know if promotion causes an increase in sales or if sales drive promotion. Put differently, as high-volume prescribers are both more likely to be detailed by manufacturers and are more likely to be open to prescribing, it is unknown which variable drives the other. (Ex. 2, Rosenthal Dep. at 330:25–331:13.)

Rosenthal admits that she never tested for endogeneity, even though she concedes that such tests exist. (Ex. 2, Rosenthal Dep. at 336:16–337:21.) In fact, she has tested for endogeneity in numerous other cases using a test called the "instrumental variables methodology." (*Id*. at 337:22–338:4.) Yet she did not employ that or any other test here.[4] Rosenthal's failure to test her theories renders her opinions unreliable.

In her indirect regression model, Rosenthal attempts to explain the effect of marketing on opioid prescriptions by supposedly accounting for all of the other variables that possibly could

[4] As she stated, "Q. What have you done to answer the individualized question of whether targeting certain physicians by the manufacturers in this case was the cause of additional MMEs as opposed to the effectiveness of the marketing overall? A. That question is not relevant to my charge. I want to understand what is the total effect. I have -- I do not know why the court would want to understand what aspects of targeting of specific physicians that drive marketing increases." (Ex. 2, Rosenthal Dep. 86:9–21.)

explain the increase in opioid prescriptions over the two decades that she examines. (*See* Ex. 1, Rosenthal Report at ¶ 79.) Yet Rosenthal omits key variables that might explain the increase in opioid prescriptions over the relevant time period (*e.g.*, the number of military veterans, doctors, hospitals, or pill mills in a Track One County). Her omissions include variables that Plaintiffs allege drove the increase, like the medical guidelines for the treatment of pain (*see* Ex. 2, Rosenthal Dep. at 670:2–5) and the increase in surgery- and trauma-related opioid prescriptions that she decided to include in her "thought experiment" (*id.* at 567:23–568:21). They also include external factors that she concedes might drive physicians' prescribing habits, like patient preference, loyalty to certain classes of drugs, and drug reimbursement policy. (*Id.* at 89:3–90:1.) *See Reed Const. Data Inc. v. McGraw-Hill Cos.*, 49 F. Supp. 3d 385, 400 (S.D.N.Y. 2014) ("to be admissible, a regression analysis must control for the 'major factors' that might influence the dependent variable"), *aff'd*, 638 F. App'x 43 (2d Cir. 2016). It is thus unsurprising that her indirect model estimates that 67 percent of all opioid prescriptions dispensed are attributable to Defendants' aggregate marketing efforts—over 20 percent more than her direct model estimates. (*See* Ex. 1, Rosenthal Report at Table 2 & Table 3.) The wildly divergent outcomes of her two models highlight that neither is the result of sound economic methodology for regression models.

III. CONCLUSION

For the foregoing reasons, the Court should exclude Rosenthal's opinions and proposed testimony.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Donna M. Welch, hereby certify that the foregoing document was served via the Court's ECF system to all counsel of record.

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